Exhibit 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707	11/7/2016-11/18/2016*
	FEI NUMBER 1110315

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Ms. Reem Malki , Head of Global Quality Operations

FIRM NAME	STREET ADDRESS
Mylan Pharmaceuticals Inc.	781 Chestnut Ridge Rd
CITY, STATE, ZIP CODE, COUNTRY Morgantown, WV 26505-2730	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, adequate controls have not been instituted over electronic systems in your analytical laboratories:

1. Batches are retested by analysts that may result in passing results being obtained. We observed instances of batches subject to out-of-specification (OOS), out-of-trend (OOT) and other anomalous results that were retested without any investigation. Examples include:

   a) Lot 3070227 of Amlodipine Besylate Tablets, 10 mg – the content uniformity testing of this batch yielded a failing result such that the USP <905> criteria was not met. Without initiating an investigation, the chemist re-injected the sample and reported the passing test result.

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	Massoud Motamed, Investigator Pratik S Upadhyay, Investigator Chaltu N Wakijra, Investigator Atul Agrawal, Investigator	11/18/2016

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This same sample set displayed "Data Missing" for another injection for content uniformity.

b) Lot 3065475 of Glyburide Tablets, 3 mg – the assay testing of this batch yielded results that failed to meet the specification of [redacted] Your Director of Quality Control acknowledged the result was not within specification. Without initiating an investigation, the chemist re-injected the sample and reported the passing test result.

c) Lot 3060192 of Zonisamide Capsules, 100 mg – the assay testing of this batch yielded a failing result of [redacted] Your firm's Quality Unit employees stated this result was aberrant due to a retention difference; however, the failing result met your firm's specification for retention difference. Without initiating an investigation, the chemist re-injected the sample and reported the passing test result.

d) Lot 2006314 of Atenolol Tablets, 50 mg – the assay testing of this batch yielded an OOT result for the difference between the two assay injections, displaying a difference of [redacted] Without initiating an investigation, the chemist re-injected the sample and reported the passing test result.

e) Lot 3070215 of Amlodipine Besylate Tablets, 10 mg – the content uniformity testing of this batch yielded an [redacted] Subsequently, the test was repeated with passing results that did not display [redacted] No investigation was conducted.

f) Lot 3076881 of Glimepiride Tablets, 1 mg – the blend testing of this batch yielded [redacted] Subsequently, the test

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was repeated with passing results that did not display [redacted] No investigation was conducted.

g) Lot 2006634 of Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate & Amphetamine Sulfate Tablets, 10 mg – the blend testing of this batch yielded [redacted] Subsequently, the test was repeated with passing results that did not display [redacted] No investigation was conducted.

[redacted]

h) Lot 3063735 of Alfuzosin Hydrochloride Extended Release Tablets, 10 mg – the assay testing for this batch displayed no desired peak. Subsequently, the test was re-injected with passing results. No investigation was conducted.

i) Lot 3075884 of Amlodipine Besylate Tablets, 5 mg – the content uniformity testing of this batch yielded no desired peak. Subsequently, the test was re-injected with passing results. No investigation was conducted.

j) Lot 3079153 of Amlodipine Besylate Tablets, 5 mg – the assay testing of this batch yielded no desired peak. Subsequently, the test was re-injected with passing results. No investigation was conducted.

k) Lot 2005571 of Atorvastatin Calcium Tablets, 10 mg – the dissolution testing of this batch yielded no desired peak. Subsequently, the test was rey-injected with passing re-

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sults. No investigation was conducted.

l) Lot 2005373 of Atorvastatin Calcium Tablets, 80 mg – the related compounds test of this batch yielded a [redacted] for the initial injection (the run was not aborted). Subsequently, the test was re-injected with passing results. No investigation was conducted.

m) Lot 3067498 of Atenolol Tablets, 50 mg – the assay testing of this batch yielded [redacted]' for the initial injection (the sample had been injected). Subsequently, the test was re-injected with passing results. No investigation was conducted.

n) Lot 2005347 of Amlodipine and Benzapril Hydrochloride Capsules, 5 & 10 mg – the assay testing of this batch yielded [redacted] for the initial injection (the run was not aborted). Subsequently, the test was re-injected with passing results. No investigation was conducted.

[redacted]

Throughout the inspection, we observed additional instances of re-injecting samples due to anomalous events results with no corresponding investigation(s).

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All lots specifically referenced above have been released.

2. We observed in both the Quality Control and R&D laboratories the practice of conducting injections on HPLCs and GCs prior to official analyses. Both laboratories operate under Good Manufacturing Practices, including validation studies, stability testing and finished product testing. Members of the Quality Control Unit stated that the injections conducted prior to official analyses are for the purpose of instrument setup. However, we observed many injections in both QC and R&D conducted prior to official analyses that are not identified with a name or identified in an obscure manner (e.g., "TEST," "New MP test injects LMFAO," "Medium," "Besylate ID," "lop," "0" "Single Sample," "o," "1". Based on the large number of analyses conducted, a review of all of these injections prior to official analyses was not feasible. We randomly selected and reviewed some of these injections and observed that the area values for them are similar to standards and samples run during the official analyses.

   Based on samples and standards chromatograms appearing similar, there is no evidence to prove that the injections conducted prior to official analyses are not trial injections of the official samples.

3. Analysts in the Quality Control laboratory maintain the practice of altering sample sets for significant changes (e.g., sample weight, composite weight, dilution factor, etc.). Every instance of altered sample sets could not be reviewed based on the large number of instances. There is no evidence that the alterations to sample sets are reviewed to determine whether they were conducted for valid reasons and if they had/have a significant impact on the analytical results being reported. For example, we observed extensive alterations after the completion of the runs in the analysis of the following products:

   a) Ketoconazole – Lots 3067506, 3062386 and 3051648; analyzed in September 2016; pa-

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rameters altered parameters include composite weight, dilution factor, number of units composited and sample weight.

b) Valsartan HCTZ – Lots 2005689; analyzed in October 2016; parameters altered include the dilution factor, sample ID, test ID, sample name, composite weight and sample weight.

c) Felodipine – Lot 3060356; analyzed in August 2016; parameters altered include the composite weight, number of units composited and sample weight.

OBSERVATION 2

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

a) The Quality Unit maintains shredding bins in the following areas: Quality Control (QC), Quality Assurance (QA), Environmental Health and Safety (EHS), Packaging and Manufacturing areas. On November 16, 2016, we found numerous documents in the shredding bins. Based on the sheer volume, each document could not be reviewed and verified during the current inspection. Examples of documents we found include:

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[redacted]

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

(1) We reviewed [redacted] f your firm's unconfirmed out-of-specification (OOS) reports pertaining to related compound testing and observed [redacted] o be attributed to "Glassware Contamination." This attribution of OOS results to glassware contamination has been a continued practice at your firm with no effective resolution, and is utilized to invalidate failing results.

Some Examples of Trending Assessments are as follows:

a) Trending Assessment [redacted] opened on May 15, 2015 was opened for attribution of OOS results to dirty glassware and resolved to provide additional training on glassware cleaning.

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b) Trending Assessment [redacted] opened on July 23, 2015 identifies a trend of invalidating OOS results due to an attribution to dirty glassware and recommends a laboratory-wide retraining on glassware cleaning.

c) Trending Assessment [redacted] opened on December 18, 2015 identifies a trend of invalidating OOS results due to an attribution to dirty glassware and concludes that retraining on cleaning practices will occur.

All trending assessments indicate that this trend had been previously identified and is an ongoing issue. In total, [redacted] trending assessments identifying the attribution of OOSs to dirty glassware have been conducted since May of 2015.

Coincidently, of these [redacted] OOS results, at least [redacted] discussed instrument malfunction and dirty glassware during analysis which led to the generation of the OOS result. It is unclear how your firm's Quality Unit invalidates OOS results when a root cause is not defined and multiple failures are implicated.

Notably, of these [redacted] OOS results, at least [redacted] had analysts that did not report the initial failing result or mis-process the analytical data pertinent to the OOS results. Given the identification of the mis-handling of analytical data by these analysts, your Director of Analytical Investigations stated no assessment of the analyst's previous and other work had been conducted.

(2) Your firm manufactures drug products, despite an awareness of manufacturing investigation reports and complaints related to known repeated manufacturing deficiencies. Examples of these deficiencies include:

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[redacted]

OBSERVATION 4

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically,

Analysis for the following are conducted using non-validated and non-verified analytical test methods:

a) Process Validation (PV) batches

b) Regulatory submission batches

c) Active Pharmaceutical Ingredients (APIs)

d) In-process test samples

e) Finished products

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f) Stability samples

We found instances in which your firm's R&D laboratory performed validation of test methods in time periods of several months to two years after issuance of the Certificate of Analyses (CoAs). These changes affected the parameters of the method, such that the methods may have been materially different. The following are five examples covered during the inspection:

a) **Estradiol Vaginal Cream USP, 0.01% (ANDA: 208788)**

Process Validation batches: [redacted]

Test Name	Method	Initial Validation Report Dated	Current Validation Report Dated	PV/Exhibit batch testing Dated
[redacted]	[redacted]	10/14/15	10/20/15	[redacted]
		04/02/15	09/21/15	
		03/09/15	09/23/15	
		07/24/15	10/26/15	
		05/07/15	12/15/15	

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[redacted]	03/09/15	04/08/15	
	10/21/15	10/21/15	
	10/14/15	10/21/15	

b) Colchicine Tablets USP, 0.6 mg (ANDA: 209470)

Process Validation batches: [redacted]

Test Name	Method	Initial Validation Report Dated	Current Validation Report Dated	PV/Exhibit batch testing CoAs Issued Date
[redacted]	[redacted]	01/28/15	04/21/16	[redacted]
		02/15/16	06/15/16	
		02/01/16	04/19/16	
		02/04/16	05/12/16	

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[redacted]	01/28/15	04/21/16	
	02/15/16	06/15/16	
	02/19/15	04/19/16	

c) **Clindamycin Palmitate Hydrochloride for Oral Solution, USP 75 mg/5ml (ANDA: 203063)**

Process Validation batches: [redacted]

Test Name	Method	Initial Validation Report Dated	Current Validation Report Dated	Method Transfer (QC lab) Dated	PV/Exhibit batch testing CoA release Dated
[redacted]		NA	NA	10/19/12	[redacted]
		NA	NA	10/19/12	
		04/01/11	04/01/11	10/19/12	
		04/01/11	04/05/11	10/19/12	

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[redacted]	04/05/11	04/05/11	10/19/12
	04/01/11	04/01/11	10/19/12
	10/13/11	09/26/14	12/01/14
	04/01/11	04/01/11	10/19/12
	NA	NA	10/19/12
	04/04/11	04/05/11	10/19/12
Malvern)	02/03/11	02/03/11	10/19/12

d) Dextroamphetamine Sulfate, USP API/Dextroamphetamine Sulfate Extended-Release Capsules (ANDA: 206735)

Process Validation batches: [redacted]

Test Name	Method	Initial Validation Report	Current Validation Report	Method Transfer (QC lab)	PV/Exhibit batch testing

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707	11/7/2016-11/18/2016*
	FEI NUMBER 1110315

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Ms. Reem Malki , Head of Global Quality Operations

FIRM NAME	STREET ADDRESS
Mylan Pharmaceuticals Inc.	781 Chestnut Ridge Rd
CITY, STATE, ZIP CODE, COUNTRY Morgantown, WV 26505-2730	TYPE ESTABLISHMENT INSPECTED Finished Drug Product Manufacturer

[redacted]	Dated	Dated	Dated	Dated
[redacted]	12/03/13	12/03/13	06/02/15	
[redacted]	12/17/13	12/17/13	06/02/15	
[redacted]	n/a	n/a	06/02/15	
[redacted]	12/17/13	12/17/13	06/02/15	[redacted]
[redacted]	12/18/13	12/18/13	06/02/15	[redacted]
[redacted]	10/30/13	10/30/13	04/23/15	[redacted]
[redacted]	04/06/15	04/06/15	04/22/15	[redacted]
[redacted]	09/11/15	09/11/15	04/23/15	
[redacted]	11/25/13	11/25/13	04/23/15	
[redacted]	11/25/13	11/25/13	04/23/15	

e) **Memantine Hydrochloride ER Capsules, 7mg, 14mg, 21mg and 28mg (ANDA: 206032)**

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Process Validation batches: [redacted]

Test Name	Method	Initial Validation Report Dated	Current Validation Report Dated	Method Transfer (QC lab) Dated	PV/Exhibit batch testing CoAs issued Dated
[redacted]		09/21/07	12/03/13	09/21/07	
		07/15/14	12/17/13	09/03/14	[redacted]
		08/23/07	n/a	09/13/07	
		08/20/14	12/17/13	09/23/14	
		09/18/07	12/18/13	09/18/07	
		07/03/13	10/30/13	07/15/13	
		05/31/13	04/06/15	07/15/13	
		06/11/13	09/11/15	07/15/13	

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[redacted]	06/21/13	11/25/13	07/15/13	

OBSERVATION 5

Complaint records are deficient in that they do not include the known nature of complaint.

Intake reports pertaining to consumer complaints are subjectively reviewed and do not accurately capture the complaint to address potential product quality impact. This practice allows for investigations to invalidate the consumer complaints inappropriately. Examples are as follows:

a) [redacted]

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A [redacted]
S[redacted]

***DATES OF INSPECTION**

11/07/2016(Mon),11/08/2016(Tue),11/09/2016(Wed),11/10/2016(Thu),11/11/2016(Fri),11/14/2016(Mon),11/15/2016(Tue),11/16/2016(Wed),11/17/2016(Thu),11/18/2016(Fri)

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